IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT WHEELING

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP, *Plaintiffs*, v. MYLAN PHARMACEUTICALS INC. and KINDEVA DRUG DELIVERY L.P., *Defendants*.	Civil Action No. 1:22-CV-35-JPB

DEFENDANTS' PROPOSED FINDINGS OF FACT, CONCLUSIONS OF LAW AND [PROPOSED] FINAL JUDGMENT

Table of Contents

Pursuant to the Court's correspondence dated November 7, 2022, Defendants Mylan Pharmaceuticals Inc. and Kindeva Drug Delivery L.P. (collectively, "Mylan" or "Defendants") hereby submit their Proposed Findings of Fact and Conclusions of Law.

I. BACKGROUND

A. The Parties

PFOF 1. Plaintiff AstraZeneca AB is a corporation organized and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

PFOF 2. AstraZeneca AB is the current assignee and owner of U.S. Patent No. 11,311,558 ("the '558 patent").

PFOF 3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

PFOF 4. Mylan Pharmaceuticals Inc. ("Mylan") is a company organized and existing under the laws of the State of West Virginia, with a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

PFOF 5. Defendant Kindeva Drug Delivery L.P. ("Kindeva") is a company organized and existing under the laws of the State of Delaware, with a place of business at 42 Water Street, Building 75, St. Paul, Minnesota 55170.

B. Mylan's ANDA

PFOF 6. Mylan filed an Abbreviated New Drug Application, ANDA No. 211699 ("Mylan's ANDA"), with the U.S. Food and Drug Administration on June 26, 2018, seeking approval to market generic versions of AstraZeneca's Symbicort® inhalation products ("Mylan's ANDA Products").

PFOF 7. Mylan's ANDA received final FDA approval on March 15, 2022.

PFOF 8. Mylan's ANDA received final FDA approval before the '558 patent issued.

PFOF 9. Mylan's ANDA received final FDA approval before the '558 patent was submitted by AstraZeneca to the FDA for listing in connection with Symbicort in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book.").

C. The '558 Patent

PFOF 10. The '558 patent is entitled "Composition for Inhalation" and was issued by the United States Patent and Trademark Office ("PTO") on April 26, 2022.

PFOF 11. The '558 patent issued from U.S. Application No. 16/832,590 ("the '590 application"), filed with the PTO on March 27, 2020.

PFOF 12. The '558 patent claims priority to Swedish patent application 0200312 (the "312 application"), filed on February 1, 2002, and expires on January 29, 2023.

D. Procedural History of the Case

PFOF 13. AstraZeneca filed its Complaint in this matter on the same day that the '558 patent issued—April 26, 2022. *See* ECF No. 1.

PFOF 14. In the Complaint, AstraZeneca asserts that (1) the submission of Mylan's ANDA to the FDA constituted infringement of the '558 patent under 35 U.S.C. § 271(e)(2)(A); and (2) the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products would infringe the '558 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g). *See* ECF No. 1 ¶¶ 54-65.

PFOF 15. AstraZeneca originally asserted infringement of claims 1-7, 12 and 13 of the '558 patent (the "Originally Asserted Claims").

PFOF 16. AstraZeneca subsequently identified a narrower set of claims, claims 1, 3, 4, 7, and 12 of the '558 patent (the "Asserted Claims"), as the claims it intended to assert at trial.

PFOF 17. Mylan asserted defenses and counterclaims that the Asserted Claims are invalid, claim 12 of the '558 patent is not infringed by Mylan's ANDA Products, and that there is no act of infringement under 35 U.S.C. § 271(e)(2).

PFOF 18. On November 23, 2022, the Court issued a Memorandum Opinion and Order (ECF No. 204) (the "Claim Construction Order"), construing the term "pharmaceutical composition," as recited by all claims of the '558 patent, to, *inter alia*, "not include a functional stability requirement."

PFOF 19. In the Claim Construction Order the Court also construed the term "about 0.001% w/w," as recited by claim 12 of the '558 patent, to mean "approximately" 0.001%;

PFOF 20. On October 20, 2022, Defendants filed a Motion for Partial Summary Judgment that the filing of Mylan's ANDA was not an act of infringement under 35 U.S.C. § 271(e)(2), because, *inter alia*, Mylan's ANDA was fully approved before the issuance of the '558 patent (ECF Nos. 156-157) (the "Motion").

PFOF 21. On December 5, 2022, the Court issued its Memorandum Opinion and Order (ECF No. 223) ("Summary Judgment Opinion") concluding that "Mylan supplemented the ANDA by submitting two 'Prior Approval Supplements' after the patent-at-suit issued. Such an act is a qualifying act of infringement under § 271(e)(2)(A). Clearly there is a patent in place and clearly an ANDA infringes it." Summary Judgment Opinion 20.

II. THERE ARE NO LIABILITY ISSUES FOR TRIAL

PFOF 22. On December 12, 2022, the parties jointly filed a Stipulation of Liability (ECF No. 229) that resolved all outstanding liability issues to be tried in this case. With all liability issues resolved, there are no witnesses to be called at trial.

III. SCOPE OF RELIEF IN DISPUTE

PFOF 23. On December 1, 2022, AstraZeneca submitted a status report opposition (ECF No. 219-1), which attached a proposed final form of judgment (ECF No. 219-2). Defendants object to AstraZeneca's proposed final judgment as *inter alia* overly broad, and unsupported by the law or facts of this case.

PFOF 24. On December 1, 2022, Defendants contacted the Court to request the opportunity to respond. That request was denied later that same day.

PFOF 25. On December 5, 2022, the Court held a pretrial conference and briefly heard argument relating to the scope of relief, but indicated that it believed there were still disputed issues remaining for trial, then scheduled to begin on December 13, 2022.

A. Scope of Patent Term and Patent Term Extensions

COL 1. This case involves two separate statutory schemes: the Patent Act, 35 U.S.C. §§ 1 *et seq*., and the Federal, Food, Drug and Cosmetic Act, as amended by the Hatch-Waxman Act and the Medicare Modernization Act of 2003, 21 U.S.C. §§ 301 *et seq.* (the "Hatch-Waxman Act"). Each Act sets forth a defined set of rights granted by Congress. And each has its own specialized terms of art. While the two Acts need to be read in light of each other, a right granted under one Act cannot be imputed as a right granted under the other, unless Congress has authorized that result. Moreover, the "infringement" section of Title 35, 35 U.S.C. § 271, includes provisions specific to the Hatch-Waxman Act, *e.g*., § 271(e).

COL 2. As discussed below, a patent's term defines the period during which a patentee has the exclusive right to make, use, sell, offer for sale, or import a patented invention. It accordingly limits the period in which a court may award injunctions and damages to enforce those rights.

B. Patent Term

COL 3. Patent terms are governed by 35 U.S.C. §§ 154 and 156. Under 35 U.S.C. § 154(a)(1), a patent grants the –

> right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

COL 4. The patent's exclusive right "shall be for a term beginning on the date on which the patent issues and ending 20 years from" the filing of its earliest eligible priority date. *See* 35 U.S.C. § 154(a)(2). The requirement that a patent's exclusive right be only for a "limited" time is set forth in the Constitution. U.S. Const. art. I, § 8.

PFOF 26. The term of the '558 patent expires on January 29, 2023.

C. Patent Term Extensions

COL 5. Base patent terms may be adjusted or extended under two circumstances. *First*, the term of a patent may be adjusted due to delay in issuance by the PTO resulting from its examination of a patent application. *See* 35 U.S.C. § 154(b). Thus, when the term of a patent is shortened on the front end due to PTO delay, the term can be adjusted by adding an equal amount of time to the back end of the patent's normal term.

COL 6. *Second*, the Hatch-Waxman Act established a framework by which a patent's term may be extended in certain circumstances to recapture useable patent life lost during delays in FDA regulatory review of a New Drug Application ("NDA"). S*ee* 35 U.S.C. § 156; *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-70 (1990) (When a patent "relates to a product that cannot be marketed without substantial testing and regulatory approval, the 'clock' on his patent term will be running even though he is not yet able to derive any profit from the invention."). The Hatch-Waxman Act addressed this lost patent life by extending a patent term up to five years

if, *inter alia*, the product was "subject to a regulatory review period before its commercial marketing or use," and "the permission for the commercial marketing or use of the product after such regulatory review period [was] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." 35 U.S.C. § 156(a); *see also Eli Lilly*, 496 U.S. at 669-71.

PFOF 27. The term of the '558 patent was not adjusted or extended under either § 154 or § 156 of the Patent Act.

PFOF 28. Therefore, after January 29, 2023, the '558 patent no longer "exclude[s] others from making, using, offering for sale, or selling the invention throughout the United States, or importing into the United States." 35 U.S.C. § 154(a)(1).

D. FDA Pediatric Exclusivity under the Hatch Waxman Act

COL 7. Unlike patent extensions, which are governed by Title 35, pediatric exclusivity is a regulatory privilege authorized under Title 21 ("Food and Drugs").

COL 8. Under 21 U.S.C. § 355a(c)(1), the FDA may ask a supplier of an FDA-approved drug to perform studies on the use of the drug in children.

COL 9. If the drug manufacturer complies, the FDA *may* grant a period of Pediatric Exclusivity that delays the date on which the FDA will approve an Abbreviated New Drug Application (ANDA) in certain circumstances defined by Congress. *See* § III.D.1, *infra*.

COL 10. A delayed ANDA approval date is the extent of pediatric exclusivity. Without ANDA approval, a generic manufacturer cannot market its drug. 21 U.S.C. § 355a. FDA approval is *not* needed to manufacture a drug. Pediatric exclusivity is awarded by the FDA, not by the courts or the PTO. And although an award of regulatory pediatric exclusivity may effectively extend a branded drug maker's commercial monopoly by keeping a generic drug maker's product off the

market until the FDA approves its ANDA, it does not extend the patent term itself nor prohibit the manufacture of the generic drug. *See* § III.D.2, *infra*.

1. When Pediatric Exclusivity Is Awarded

COL 11. Pediatric exclusivity may be granted only in certain scenarios. In the Pediatric Exclusivity Act, Congress set forth six circumstances in which a 6-month period of marketing exclusivity will apply—three of which involve other FDA-granted exclusivity periods and three which involve certifications related to Orange Book listed patents.

COL 12. Under the first three circumstances, the Pediatric Exclusivity Act provides an additional six months of exclusivity to an *already-awarded* FDA exclusivity:

[1] **New Chemical Entity ("NCE") Exclusivity**. A 6-month period of exclusivity will be added to the NCE periods set forth in 21 U.S.C. § 355j(5)(F)(ii). *See* 21 U.S.C. § 355a(c)(1)(A)(i)(I).

[2] **Three-year marketing exclusivity**. A 6-month period of exclusivity will be added to the three-year marketing exclusivity periods set forth in 21 U.S.C. § 355j(5)(F)(iii) and (iv). *See* 21 U.S.C. § 355a(c)(1)(A)(i)(II).

[3] **Orphan Drug Exclusivity ("ODE")**. A 6-month period of exclusivity will be added to the ODE periods set forth in 21 U.S.C. § 360cc(a). *See* 21 U.S.C. § 355a(c)(1)(A)(ii).

21 U.S.C. § 355a(c)(1)(A)(i).[1]

COL 13. None of the above-three circumstances apply in this case because the FDA has not awarded AstraZeneca any of those other three specified forms of exclusivity.

COL 14. In the other three circumstances, the additional 6-month period of exclusivity is tied to the ANDA holder's submission of a certification under 21 U.S.C. § 355(j)(2)(A)(vii). Section 355a(c)(1)(B)(i) applies a 6-month marketing exclusivity,

if the drug is the subject of—

[1] The provisions set forth in 21 U.S.C. § 355a(b)(1) et seq. mirror those set forth in § 355a(c).

> [4] (I) a listed patent for which a certification has been submitted under subsection[] … (j)(2)(A)(vii)(II)" [a so-called "Paragraph II certification"]; or
>
> [5] (II) a listed patent for which a certification has been submitted under subsection[] … (j)(2)(A)(vii)(III)" [a so-called "Paragraph III" certification].

21 U.S.C. § 355a(c)(1)(B)(i)(emphasis added).

COL 15. If a Paragraph II or III certification has been submitted, then "the period during which an application may not be approved under … section 355(j)(5)(B) of this title shall be extended by a period of six months after the date the patent expires (including any patent extensions)." 21 U.S.C. § 355a(c)(1)(B)(i).

COL 16. Section 355a(c)(1)(B)(ii) applies to certifications submitted under § 355(j)(2)(A)(vii)(IV) – a so-called Paragraph IV certification. Subsection (ii) states that

> [6] if the drug is the subject of a listed patent for which a certification has been submitted under subsection … (j)(2)(A)(vii)(IV) of section 355 of this title, and in the patent litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under … section 355(j)(5)(B) of this title shall be extended by a period of six months after the date the patent expires (including any patent extensions).

21 U.S.C. § 355a(c)(1)(B)(ii).

COL 17. No provision of the Pediatric Exclusivity Act authorizes the addition of a 6-month period of exclusivity corresponding to a patent listed in the Orange Book when a certification regarding the patent has ***not*** been submitted with the ANDA. "The effect of the grant of pediatric exclusivity [thus] depends on the type of certification included in the ANDA." *AstraZeneca AB v. Impax Lab'ys, Inc.*, 490 F. Supp. 2d 368, 372 (S.D.N.Y. 2007). In particular, Congress made a Paragraph II, III or IV certification a prerequisite to pediatric exclusivity that applies after the patent expires. Without one of those certifications, there can be no additional regulatory pediatric exclusivity period following the expiration of a patent.

PFOF 29. Because Mylan's ANDA had already received final FDA approval before the '558 patent was issued, and consequently before the patent was listed in the Orange Book, Mylan submitted no certification regarding the '558 patent. *See* 21 C.F.R. §314.94(a)(12)(viii)(C)(2).

PFOF 30. Therefore, no provision of § 355a(c)(1) applies to Mylan's ANDA.

PFOF 31. As such, there is no factual or legal basis for the FDA or anyone else to apply the Pediatric Exclusivity Act to prohibit Mylan for marketing and selling its generic Symbicort's products after the '558 patent's expiration on January 29, 2023.

2. Pediatric Exclusivity Does Not Prohibit the Manufacturing or Use of A Patented Invention

COL 18. Even if pediatric exclusivity could be triggered in these circumstances, it cannot apply to anything other than FDA's approval of the ANDA required to market the generic product. That is because a "pediatric exclusivity period is not an extension of the term of the patent." *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1343 (Fed. Cir. 2015) (citing 21 U.S.C. § 355a(o)(1) ("distinguishing patent exclusivity from non-patent exclusivity")); *see also Daiichi Sankyo v. Mylan Pharms. Inc.*, No. 06-3462, 2016 WL 6138241, at *4 n.1 (D.N.J. Oct. 20, 2016) ("Pediatric exclusivity ... is not a patent term extension under 35 U.S.C. § 156.") (citing *FDA, Guidance for Industry Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act* (Sept. 1999) at 13).

COL 19. Indeed, both FDA and the courts have recognized that FDA lacks the expertise to determine matters of substantive patent law.[2]

[2] *See, e.g., Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406-07 (2012) ("According to [FDA], it lacks 'both the expertise and the authority' to review patent claims; although it will forward questions about the accuracy of a use code to the brand, its own 'role with respect to patent listing is ministerial.'" (cleaned up)); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002) ("FDA has no expertise in making patent law judgments."); *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001) ("The FDA, pursuant to longstanding practice and its own regulations, and based on its acknowledged lack of expertise and resources,

COL 20. The distinction is important because patent protection and regulatory exclusivities are not co-extensive. While a patent is in force, the patentee has the right to exclude others from making, using, selling, offering for sale, or importing the patented product (*see* §§ III.A-C, *supra*)—and in appropriate circumstances may obtain an injunction to enforce that exclusive right during the patent's term. Regulatory exclusivity is much more limited in scope, as FDA approval is necessary only to "introduce [a new drug] or deliver [it] for introduction into interstate commerce." 21 U.S.C. § 355a; *see also In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239 (3d Cir. 2012) ("The FDCA ... provides that a drug cannot be *sold in interstate commerce* unless it is approved by the FDA …." (emphasis added)).

COL 21. Accordingly, once a patent on a pharmaceutical compound or product has expired, a generic competitor is free to manufacture that product, package it, label it, and prepare to sell it in this country before receiving FDA approval. *See Altana Pharma AG v. Teva Pharms. USA, Inc.*, No. 04-2355, 2012 WL 2068611, at *2 (D.N.J. June 7, 2012) (distinguishing the prohibition on marketing a drug during the pediatric exclusivity period from the bundle of exclusive patent rights that do not apply once a patent has expired regardless of a continuing pediatric exclusivity period); *AstraZeneca*, 782 F.3d at 1343 ("We have long held that 'there can be no infringement once the patent expires,' because 'the rights flowing from a patent exist only for the term of the patent.'" (citation omitted)).

COL 22. In *Daiichi Sankyo v. Mylan Pharmaceuticals Inc.*, the district court found that Daiichi Sankyo's patent was valid and infringed, and issued a final judgment that included the following injunction:

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has refused to become involved in patent listing disputes …."); *Watson Pharms., Inc. v. Henney*, 194 F. Supp. 2d 442, 445-46 (D. Md. 2001) ("[FDA] has no expertise—much less any statutory franchise—to determine matters of substantive patent law.").

> **ORDERED** that, pursuant to 35 U.S.C. § 271(e)(4)(B), Mylan, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are enjoined, *until the expiration date of the '599 patent, including all extensions thereof*, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the products which are subject of ANDA Nos. 78-276, 78-827, and 90-398.

2016 WL 6138241, at *1 (emphasis added).

COL 23. In *Daiichi*, because the injunction on the manufacturing and use expired when the patent and any patent term extensions expired, Daiichi Sankyo (the patentee) moved the court to amend the judgment under Fed. R. Civ. P. 60(a) to extend the injunction to the expiration of the pediatric exclusivity period, i.e., October 25, 2016. *See, e.g.*, *id*. at *2. But the court denied Daiichi Sankyo's motion, observing that "[t]he FDA's grant [of pediatric exclusivity] did not extend the injunction issued by this Court, as the FDA's own guidance makes clear." *Id*. at *4. The court also noted that "Daiichi Sankyo now asks the Court to impute the pediatric exclusivity grant to the Judgment, as a *de facto* extension of the Court's injunction, which it clearly is not." *Id*. at *4 n.1.

PFOF 32. Thus, even if AstraZeneca could claim pediatric exclusivity even though Mylan did not file a certification, the Court cannot prohibit the manufacturing of Mylan's ANDA products after the '558 patent expires on January 29, 2023.

E. Any Injunction under § 271(e)(4)(B) Must End When the Patent Expires

COL 24. Section 271 of the Patent Act, 35 U.S.C. § 271, specifies what acts constitute infringement of a U.S. patent. In general, one who (without a license) makes, uses, sells, offers to sell, or imports a patented invention in the United States "during the term of the patent therefor" commits patent infringement, 35 U.S.C. § 271(a), and courts may award remedies for infringement including injunctions, damages, and attorneys' fees under 35 U.S.C. §§ 283 (injunctions), 284 (damages), and 285 (attorneys' fees).

COL 25. Section 271(e)(2), however, contains a special provision establishing a "highly artificial" act of infringement when a drug company submits an ANDA seeking FDA approval to market a generic version of an approved patented drug, even if it has not yet made or sold the drug. *See Eli Lilly*, 496 U.S. at 678.

COL 26. If a court finds that the proposed ANDA product would infringe a valid patent, the court may award remedies as set forth in Section 271(e)(4), including:

- an order making the effective date of FDA approval of the generic drug "not earlier than the date of the expiration of the patent which has been infringed," 35 U.S.C. § 271(e)(4)(A);
- "injunctive relief may be granted against *an infringer* to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product." 35 U.S.C. § 271(e)(4)(B)(emphasis added); and
- "damages or other monetary relief may be awarded against *an infringer* only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product." 35 U.S.C. § 271(e)(4)(C) (emphasis added).

COL 27. Sections 271(e)(4)(B) and (e)(4)(C) "provide the 'typical remedies' for patent infringement: injunctive relief and money damages." *AstraZeneca*, 782 F.3d at 1342 (citation omitted).

COL 28. The remedies in Section 271(e)(4) are the "only remedies," apart from attorneys' fees, that may be awarded for the artificial act of infringement established in Section 271(e)(2). 35 U.S.C. § 271(e)(4).

COL 29. It is axiomatic that a patent "infringer" under 35 U.S.C. § 271(e)(4)(B) can exist only when a patent exists to be infringed. The Federal Circuit has "long held that 'there can be no infringement once the patent expires,' because 'the rights flowing from a patent exist only for the term of the patent.'" *AstraZeneca*, 782 F.3d at 1343 (citation omitted).

COL 30. Once the patent expires, there are no longer exclusive rights to "making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States." 35 U.S.C. § 154 (defining the scope and term of the exclusive right to the patented invention); *cf. AstraZeneca*, 782 F.3d at 1344 (finding no entitlement to post-patent expiration damages "because Astra's rights during that period were not attributable to its patents and were not invaded by Apotex's [post-patent expiration] infringement.").

COL 31. In short, an injunction under 35 U.S.C. § 271(e)(4)(B) (or 35 U.S.C. § 283) prohibiting the commercial manufacture, use, offer to sell, or sale or importation cannot extend beyond the term of the patent because the statutory injunctions all are limited to the acts of an "infringer."

COL 32. Therefore, any injunction ordered here would have to expire upon the expiration date of the '558 patent, i.e., on January 29, 2023.

F. AstraZeneca's Request That the Court Invoke Its Equitable Powers Should Be Denied

PFOF 33. AstraZeneca argues that even if 35 U.S.C. §§ 271(e)(2) & (e)(4)(A) do not apply, this Court can still enter an order resetting the final approval date of Mylan's ANDA pursuant to its general equitable powers. For the following reasons, such relief is legally impermissible.

1. Equitable Relief Was Not Pleaded

PFOF 34. In its Complaint in this action, AstraZeneca did not seek relief in the form of an order resetting the final approval date of Mylan's ANDA under the Court's general equitable powers. *See* ECF No. 1 at Prayer for Relief.

PFOF 35. In its Response to Defendants' Status Report, AstraZeneca relies on two paragraphs from the Complaint's Prayer for Relief, paragraphs D and H, as requesting this relief.

See ECF No. 219-1 at 7. Neither of those paragraphs sought relief in the form of an order resetting the final approval date of Mylan's ANDA under the Court's general equitable powers. *See* ECF No. 1 at Prayer for Relief.

PFOF 36. Paragraph D sought the "entry of an order, ***pursuant to 35 U.S.C. § 271(e)(4)(A)***, that the effective date of any FDA approval of ANDA No. 211699 shall be no earlier than the expiration date of the '558 patent, or any later expiration of exclusivity for the '558 patent, including any extensions or regulatory exclusivities." ECF No. 1 at Prayer for Relief at ¶ D (emphasis added). Paragraph D thus sought entry of an order under 35 U.S.C. § 271(e)(4)(A), not under the Court's general equitable powers.

PFOF 37. Paragraph H was a boilerplate request for "[s]uch further relief as this Court may deem just and proper." ECF No. 1 at Prayer for Relief at ¶ H. Paragraph H did not seek relief in the form of an order resetting the final approval date of Mylan's ANDA under the Court's general equitable powers.

PFOF 38. AstraZeneca has never sought leave to amend its complaint to add a request for relief in the form of an order resetting the final approval date of Mylan's ANDA under the Court's general equitable powers.

COL 33. AstraZeneca's request for relief under the Court's general equitable power is barred by its failure to request that relief in the Complaint and to seek leave to amend the Complaint to add such a request. *See Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 491-92 (1964) (failure to plead claim barred recovery of certain relief); *see also Totes-Isotoner Corp. v. United States*, 594 F.3d 1346, 1354 (Fed. Cir. 2010) (plaintiff obligated to provide the grounds of entitlement to relief).

2. AstraZeneca cannot obtain "equitable" relief that Congress chose not to provide through law

COL 34. AstraZeneca's attempt to invoke the Court's general equitable powers also fails because such powers do not apply when Congress has specified what legal and equitable relief is available and under what preconditions. Where Congress has prescribed a specific set of remedies for a violation of a statutory provision, courts cannot ignore the statutory prerequisites for such remedies and proceed to order the remedy under their general equitable powers. *See, e.g.*, *Reno v. Bossier County School Board*, 520 U.S. 471, 485 (1997) ("'[I]t is well established that 'courts of equity can no more disregard statutory and constitutional requirements and provisions than can courts of law.'''") (citation omitted).

COL 35. Pursuant to 35 U.S.C. § 271(e)(2)(A), it "shall be an act of infringement to submit" "an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent."

COL 36. Congress provided that courts may "order the effective date of" an ANDA approval "to be a date which is not earlier than the date of the expiration of the patent which has been infringed" "***[f]or an act of infringement described in***" 35 U.S.C. § 271(e)(2). *See* 35 U.S.C. § 271(e)(4)(A) (emphasis added).

COL 37. Thus, by statute, an order resetting the effective date of an ANDA approval is a remedy available for an act of infringement described in 35 U.S.C. § 271(e)(2). *See* 35 U.S.C. § 271(e)(4)(A).

COL 38. Congress expressly limited the courts' equitable powers in § 271(e)(4), which directs that "[t]he remedies prescribed by subparagraphs (A), (B), (C), and (D) are the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2),

except that a court may award attorney fees under section 285." 35 U.S.C. § 271(e)(4)(D) (emphasis added).

COL 39. AstraZeneca's request for an order resetting the final approval date of Mylan's ANDA under the Court's general equitable powers, even though 35 U.S.C. § 271(e)(4)(A) does not apply, is "an attempt to obtain through equity that which the law … forbids." *Bossier Parish Sch. Bd.*, 520 U.S. at 485. "It is well established that courts of equity can no more disregard statutory and constitutional requirements and provisions than can courts of law." *Id.* at 485 (cleaned up).

COL 40. The existence of general equitable powers "does not confer on the court unlimited authority to ignore plain statutory requirements and to alter the substantive rights of the parties." *In re Landbank Equity Corp.*, 973 F.2d 265, 271 (4th Cir. 1992).

COL 41. Indeed, the Supreme Court has recently reminded courts that they may not use their general equitable authority to order relief when "the relevant statutory scheme … contain[s] … 'elaborate enforcement provisions,' including … provisions that explicitly provide for that form of relief." *AMG Capital Mgmt. v. FTC*, 141 S. Ct. 1341, 1350 (2021) (citation omitted).

COL 42. Accordingly, when there has been no act of infringement under 35 U.S.C. § 271(e)(2), courts must and do refuse to order the relief specified in 35 U.S.C. § 271(e)(4)(A). *See Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc., USA*, 821 F.Supp.2d 681, 697 (D.N.J. 2011) (remanded on other grounds) ("This Court agrees with Defendants that 35 U.S.C. § 271(e)(4)(A) is inapplicable to this case because the infringing acts fall under 35 U.S.C. § 271(a) (direct infringement), § 271(b) (inducement), and § 271(c) (contributory infringement), not under § 271(e)(4)(A) (infringement based on the act of filing the ANDA). Accordingly, this Court will

deny Plaintiffs' request for an order changing the ANDA effective date."), *aff'd*, 784 F.3d 1354 (Fed. Cir. 2014).

COL 43. AstraZeneca's lone cited case, *AstraZeneca v. Impax Lab'ys, Inc.*, 490 F.Supp.2d 368 (S.D.N.Y. 2007), is not to the contrary. In discussing "Equitable Relief," that court stated:

> Similarly, in this case, were the Court to find the patents valid and infringed ***and issue an order pursuant to 35 U.S.C. § 271(e)(4)(A)*** directing Impax's ANDA to have a delayed effective date, such an order would have the effect of returning the parties to the status quo before infringement—that is before Impax filed its ANDA with a Paragraph IV certification.

Id. at 375-76 (emphasis added).

COL 44. Thus, even when the *Impax* court was discussing its equitable powers, it still predicated the exercise of those powers on the issuance of an order pursuant to 35 U.S.C. § 271(e)(4)(A). *See id.* at 376.

COL 45. The Court also cannot invoke its general equitable powers to issue a mandatory or prohibitive injunction to the FDA. Absent statutory authority, courts in civil suits between private parties have no power to enjoin a non-party agency of the Executive Branch. *See, e.g.*, *Commercial Sec. Bank v. Walker Bank & Trust Co.*, 456 F.2d 1352, 1355-56 (10th Cir. 1972).

IV. [PROPOSED] FINAL JUDGMENT

Although the Court has found infringement under § 271(e)(2) and has concluded that AstraZeneca is consequently entitled to relief under 35 U.S.C. § 271(e)(4), that relief cannot extend beyond the patent's expiration date on January 29, 2023. Therefore, any relief under either 35 U.S.C. § 271(e)(4)(A) and/or § 271(e)(4)(B) beyond January 29, 2023 would be improper for the reasons explained above. Recognizing Defendants' reservation of their objections and without prejudice to Defendants' reservation to appeal that order, and underlying orders thereto, and any relief granted thereto, attached hereto as Exhibit A, is a [proposed] final judgment. This proposed

order mirrors the language in *Daiichi Sankyo*, 2016 WL 6138241, at *1, which AstraZeneca acknowledged was a "model" form of final judgment. *See* AZ Response to Mylan Status Report (ECF No. 219-1) at 12.

Respectfully submitted this 12th day of December, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that, on this the 12th day of December 2022, I filed the foregoing "Defendants' Proposed Findings of Fact, Conclusions of Law and [Proposed] Final Judgment" with the Clerk of the Court using the Court's CM/ECF system, which will send notification of the same to all counsel of record.

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